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## Peer review of the report of the Ad Hoc Technical Expert Group on Synthetic Biology

>>> *Comments of German Life Science Association (VBIO e. V.)*

Dear Mrs Paşca Palmer,  
the German Life Sciences Association VBIO e. V. (Verband Biowissenschaften, Biologie und Biomedizin in Deutschland) is Germany's largest association for life sciences. It represents about 30,000 members spanning the entire spectrum of the biological sciences, from the molecular and cellular to the organismic and ecological levels, and includes the biomedical field.

German Life Science Association has been carefully following the ongoing discussions on Synthetic Biology under the umbrella of the CBD (resp. the Cartagena Protocol).

We kindly ask you to consider our comments concerning the report of the Ad Hoc Technical Expert Group on Synthetic Biology, which you will find attached.

For queries and further information, we are happy to provide additional input.

Yours sincerely,



Prof. Dr. Bernd Müller-Röber  
President VBIO

Der VBIO ist die gemeinsame Stimme der Biowissenschaften in Deutschland.  
Er vertritt die Interessen von über 30.000 Mitgliedern aus allen Bereichen der Biowissenschaften - darunter neben Einzelmitgliedern auch 27 biowissenschaftliche Fachgesellschaften und 80 Institutionen.

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**Comments on the report of the  
Ad Hoc Technical Expert Group on Synthetic Biology**

Page #	Para #	Comment
3	Head 3.1 Para #15 (a-k)	<p>The heading “recent technological developments of Synthetic Biology” suggests that all methods and technologies specified in #15 (a-k) represent specific molecular methods exclusively used in Synthetic Biology. This is by no means the case, and therefore <i>de facto</i> wrong as lit (c), (e) and (h) e. g. reflect to molecular methods which are well established standard procedures used in many fields of basic research far beyond Synthetic Biology.</p> <p>We would like to stress that the classification, whether or not a scientific project is attributed to Synthetic Biology, does by now means depend on the application of a single molecular technique. Instead it is the amalgamation of the general conceptual approach, the overall goal and the combination of different molecular methods which make a project one of “Synthetic Biology”.</p> <p>We kindly ask the ATHEG to employ a more sophisticated description for Synthetic Biology in which single molecular techniques are considered separately from basic approaches or potential applications (e. g. gene drives). This will be a precondition for an adequate evaluation of the positive and negative effects of projects which meet the conceptual definition of “Synthetic Biology” drafted above.</p> <p>It will also improve the consistency of the ATHEG views as in #22 (e. g.) the ATHEG itself seems to distinguish between Synthetic Biology and “classical genetic engineering”.</p> <p><b>Please note that all our following comments on “Synthetic Biology” will reflect on this restricted definition of “conceptual Synthetic Biology” (<i>sensu stricto</i> – s. s.).</b></p>
3	15 (c)	<p>Genome Editing in itself does not constitute an application of Synthetic Biology (<i>sensu stricto</i>). Application of Genome editing techniques can result in organisms which may fall under LMO regulation but can also lead to organisms which cannot be distinguished from natural organisms or those altered by traditional breeding techniques or mutated by natural means in the absence of human intervention.</p>
3	15 (e)	<p>“Biotechnology tools” are methods which are widely used outside the conceptual approach of Synthetic Biology (<i>sensu stricto</i>), since decades.</p>
3	15 (h)	<p>See #15 e: “Biotechnology tools” are methods which are widely used outside the conceptual approach of Synthetic Biology (<i>sensu stricto</i>).</p> <p>See #16: The speed of development within Synthetic Biology itself is not a predictor of any positive or negative consequence of Synthetic Biology – in particular if a broad description is applied.</p>

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3	16	<p>The speed of development within Synthetic Biology itself is not a predictor of any positive or negative consequence of Synthetic Biology – especially if the understanding of „Synthetic Biology“ is as wide as the definition presented in #15.</p> <p>It is neither the time nor the numbers of alterations but the function and quality of the outcome of a project which can be attributed to Synthetic Biology.</p> <p>There are well implemented regulations in many countries allowing to assess the positive and negative impacts which might arise from the outcome of a Synthetic Biology project. If certain countries do not have an appropriate regulation, this might be addressed and supported by capacity building rather than by more international or multilateral regulations.</p>
5	28	<p>See also #15c: This statement is legitimate for outcomes of Synthetic Biology (<i>sensu stricto</i>) but not for all outcomes from Genome Editing methods. Mingling up both extremes is not helpful as it obscures adequate evaluation of specific positive or negative effects.</p>
5	30	<p>Epigenetic alterations themselves do not modify DNA sequences and respective organisms should, therefore, not be regarded as LMO.</p> <p>In those rare cases in which a specific molecular technique will introduce foreign genetic material, the resulting organism might indeed be regarded as LMO.</p>
5	33	<p>It may be necessary to develop additional tools for detecting, identifying and monitoring the outcomes of Synthetic Biology (<i>sensu stricto</i>). But we do not see the rationale to identify additional tools just for those LMOs which are indistinguishable from naturally occurring or conventionally bred counterparts.</p>
general	Several (e. g. 17, 25,28, 41, 44, 51)	<p>Positive and negative effects of gene drives have to be assessed very carefully as this approach poses huge challenges for scientists as well as for the society.</p> <p>Due to the comprehensive, not very differentiated description of Synthetic Biology in #15 the complex issue of gene drives is referred to in different sections of the paper. This complicates the necessary scientific, ethical and social reflections, and in fact leads to confusion and misconception. To enable a structured discussion on gene drives, we would have preferred that the ATHEG dealt with it in a separate section of the paper.</p> <p>However, an organism with gene drive elements will fall under the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development which is reaffirmed in the Cartagena Protocol (preamble, article 1). They are considered as GMO/LMO and subject to regulation in many countries. If appropriate regulations are not established in individual countries, the precautionary principle might be appropriately addressed and supported by capacity building rather than by more international or multilateral regulations.</p>

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